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EXAMINER

KRAMER, NICOLE R

ART UNIT PAPER NUMBER

3762

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/723,903

Applicant(s)

GERBER, MARTIN T.

Examiner

Nicole R. Kramer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Drawings***

2. The drawings are objected to because Figure 5 is difficult to read (dark and blurry). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 32, and 56-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-8 of copending Application No. 10/236,578. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method

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to stimulate various pelvic floor nerves in addition to stimulating the pudendal nerve, since stimulation of various pelvic floor nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 32, and 56-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-8 of copending Application No. 10/723,316. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '316 application is merely broader than the present application (that is, the '316 application allows for lead implantation at more locations than the present application). The claims of the '316 application anticipate the claims of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-55 of

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compending Application No. 10/723,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the left and right pudendal nerves, since stimulation of pudendal nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 23-24 and 54-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-44 of compending Application No. 10/836,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '355 application is merely broader than the present application (that is, the '355 application allows for both the first and second leads to be implanted at wither the sacral or the pudendal nerves). The claims of the '355 application anticipate the claims of the present application, and thus the two claims are not patentably distinct. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 23-24 and 54-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-44 of copending Application No. 10/836,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the right or left sacral nerves as an alternative or in addition to stimulating the pudendal nerve, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 10/836,924. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the right and left sacral nerves as an alternative or in addition to stimulating the pudendal nerve, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No.

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4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 10/836,927. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the right and left sacral nerves as an alternative or in addition to stimulating the pudendal nerve, since stimulation of sacral nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 23-24 and 54-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-44 of copending Application No. 10/836,970. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one



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having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate the left and right pudendal nerves, since stimulation of pudendal nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 23-24 and 54-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-44 of copending Application No. 10/837,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one having ordinary skill in the art at the time of applicant's invention to modify the claimed method to stimulate one or more of the claimed pelvic floor nerves as an alternative or in addition to stimulating the pudendal and sacral nerves, since stimulation of various pelvic floor nerves for treating various pelvic floor disorders is well known in the art (for example, see U.S. Patent No. 4,607,639 which teaches a method for controlling bladder evacuation via electrical stimulation of sacral roots and/or pelvic floor nerves, including the pudendal nerve).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Objections***

13. Claim 26 does not end with a period.

***Claim Rejections - 35 USC § 102/103***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-2, 13-30, 32, and 44-55 are rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,454,840 ("Krakovsky et al.") or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,454,840 ("Krakovsky et al.") in view of U.S. Patent Application Publication 2005/0209652 ("Whitehurst et al.").

Krakovsky et al. discloses an implanted device called a potency package that includes a battery 40, a programmable signal circuit 42, and a pulse generator 46 (see col. 3, lines 25-35). The device may include two medical leads, the first lead connected to the pelvic splanchnic nerves (see col. 3, lines 49-55) and the second lead connected to the pudendal nerves (see col. 4, lines 5-19) (Examiner considers "medical lead" to encompass the electrode running from the implantable pulse generator to the target nerve as shown in Figures 5 and 11). Examiner considers implantation of the first medical lead to the pelvic splanchnic nerves to be "adjacent" one of the sacral nerve or branches or portions thereof, as required by claim 1 because Examiner considers the broadest reasonable interpretation of the term "adjacent" to be close but not necessarily touching. The potency package delivers electrical stimulation pulses (see col. 3, lines 35-45) in order to provide the patient with at least partial relief from erectile/sexual dysfunction.

In the alternative (that is, an alternative interpretation of the term "adjacent" which requires touching between the first medical lead and the target sacral nerve), Whitehurst et al. discloses a method and system for treatment of sexual dysfunction via application of a stimulating drug alone or in combination with electrical stimulation (see paragraph 0016). Whitehurst et al. discloses that the electrode portions and the infusion outlets may be implanted at pelvic splanchnic nerves or the second, third, and fourth sacral nerves S2, S3, and S4 (see paragraph 0100). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the potency package of Krakovsky et al. such that the first medical lead is implanted at a

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sacral nerve as taught by Whitehurst et al. in order to effectively a patient's individual case of sexual dysfunction.

With respect to claims 2 and 33, Examiner considers "unipolar lead" to encompass the electrode disclosed in Krakovsky et al.

With respect to claims 13 and 44, the lead of Krakovsky et al. necessarily has a length. Examiner considers "less than about 4 inches, about 4 inches, about 6 inches, about 8 inches, about 10 inches, about 12 inches, about 14 inches, about 16 inches about 18 inches, about 20 inches and more than about 20 inches" to encompass any possible length of a medical lead, and thus the lead of Krakovsky et al. anticipates claims 13 and 44.

With respect to claims 14 and 45, the implanted generator disclosed in Krakovsky et al. necessarily comprises an electronic circuitry architecture selected from the group consisting of a microprocessor-based architecture, a logic architecture and a state machine architecture in order to generate electrical pulses.

With respect to claim 16 and 47, the potency package contains a power source (battery 40).

With respect to claims 15, 17, 25, 27, 46, and 48, Krakovsky et al. discloses that the unit is controlled with an external control unit (see col. 3, lines 31-37).

With respect to claims 18 and 49, the medical lead is configured for percutaneous introduction and implantation within the patient (see col. 5, lines 5-27).

With respect to claims 19-22 and 50-53, see Figs. 12 and 13 that illustrate preferred pulse programs of the potency package device.

With respect to claims 23-24 and 54-55, Krakovsky et al. discloses that the potency package may contain a chamber (60), electronic pump (62), and thin tube (64) for storing and delivering a drug to the penis (see col. 4, lines 28-53).

With respect to claims 26 and 28-30, Krakovsky et al. discloses that the stimulation program for each individual patient can only be determined by testing. The doctor can vary the parameters until the pulse series produces the desired effect (see col. 3, lines 35-45 and 63-67).

With respect to claim 32, Krakovsky et al. discloses that the SCU 160 is configured to provide pulse regimes via first and second leads rather than requiring two separate stimulator housings for each lead (see Fig. 5 and associated text). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention utilize two separate stimulator housings for each lead (i.e., a first stimulator and a second stimulator), since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnman*, 168 USPQ 177, 179.

17. Claims 1-55 are rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent Application Publication 2005/0209652 ("Whitehurst et al.") or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent Application Publication 2005/0209652 ("Whitehurst et al.") in view of U.S. Patent No. 5,454,840 ("Krakovsky et al.").

Whitehurst et al. discloses a method and system for treatment of sexual dysfunction via application of a stimulating drug alone or in combination with electrical

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stimulation (see paragraph 0016). The system includes one or more control units (SCUs) that apply the electrical stimulation and/or one or more stimulating drugs to predetermined stimulation sites (see paragraph 0017). Electrodes are surgically implanted from an implantable pulse generator and one or more infusion outlets and/or catheters are surgically implanted to infuse drugs from an implantable pump (see paragraph 0017). The electrodes may be located at the distal portion of flexible leads (see Fig. 5 and associated text at paragraphs 0055 - 0061). Whitehurst et al. discloses that the electrode portions and the infusion outlets may be implanted at the pelvic splanchnic nerves or one of the second, third, and fourth sacral nerves S2, S3, and S4 (see paragraph 0100). Examiner considers implantation of a first medical lead to the pelvic splanchnic nerves to be "adjacent" one of the pudendal nerve or branches or portions thereof, as required by claim 1 because Examiner considers the broadest reasonable interpretation of the term "adjacent" to be close but not necessarily touching.

In the alternative (that is, an alternative interpretation of the term "adjacent" which requires touching between the first medical lead and the target sacral nerve), Krakovsky et al. discloses an implanted device called a potency package for electrical and/or drug stimulation in the treatment of sexual dysfunction. The device may include two medical leads, the first lead connected to the pelvic splanchnic nerves (see col. 3, lines 49-55) and the second lead connected to the pudendal nerves (see col. 4, lines 5-19). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Whitehurst et al. such that the first medical

lead is implanted at a pudendal nerve as taught by Krakovsky et al. in order to effectively a patient's individual case of sexual dysfunction.

With respect to claims 2, 6, 33, and 37, Whitehurst et al. discloses that SCU 160 may be programmed to produce either monopolar or bipolar electrical stimulation (see paragraph 0061). The stimulator case may be used as the indifferent electrode in monopolar stimulation.

With respect to claim 3 and 34, Whitehurst et al. discloses that the leads preferably contain an array of collinear electrodes (see paragraph 0061). Examiner considers this description to anticipate "multiple electrodes disposed in an areal pattern on a planar or curved surface."

With respect to claims 4-5 and 35-36, Whitehurst et al. discloses that the leads and/or catheters may have a barb as a fixation mechanism (see paragraph 0098).

With respect to claims 8 and 39, Whitehurst et al. discloses that parameters such as high frequency stimulation may be chosen to have an inhibitory effect (see paragraph 0064).

With respect to claims 9 and 40, Whitehurst et al. does not explicitly disclose that a lead extension may be utilized. Examiner takes Official Notice that lead extensions are well known in the art. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Mann et al. to utilize a lead extension in order to modify the length of a lead to a desired length for implantation.

With respect to claims 10 and 41, Whitehurst et al. discloses that the leads (70) are preferably less than 5 mm in diameter, and more preferably less than 1.5 mm in diameter (see paragraph 0061).

With respect to claims 11-13 and 42-44, Whitehurst et al. discloses that the length of the leads are not typically longer than about 150 mm (see paragraph 0055). If such leads contain 4 collinear electrodes as preferred (see 0060-0061), such inter-electrode distance and electrode surface area are necessarily within the claimed ranges of claims 10 and 11.

With respect to claims 14 and 45, SCU 160 includes a processor and other electronic circuitry that allow it to generate electrical/infusion pulses that are applied to the patient (see paragraph 0062).

With respect to claims 15, 17, 25, 27, 46, and 48, the stimulator is activated and deactivated, programmed, and tested through a hand-held programmer 200, a clinician programming system 202, or a diagnostic system 204 (see paragraph 0069).

With respect to claims 16 and 47, Whitehurst et al. discloses that stimulator 100 includes a rechargeable battery as a power source (see paragraph 0066).

With respect to claims 18 and 49, the medical leads are configured for percutaneous introduction and implantation within the patient.

With respect to claims 19 and 50, Whitehurst et al. discloses that electrical stimulation parameters may be chosen in various frequencies (see paragraph 0064).

With respect to claims 20-22 and 51-53, Whitehurst et al. discloses that the SCU 160 allows for the electrical and/or drug stimulation parameters to be adjusted as



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needed for safe and efficacious treatment (see paragraph 0063), but fails to specifically disclose the capabilities of IPG. Such IPG capabilities are well known in the art, and it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the stimulation system of Whitehurst et al. such that the IPG is capable of generating a wide range of stimulation parameters in order to effectively treat each individual's type and degree of sexual dysfunction.

With respect to claims 23-24 and 54-55, Whitehurst et al. discloses delivering drug infusion pulses to the patient via an implanted drug pump.

With respect to claims 26 and 28-31, Whitehurst et al. discloses that operation of the stimulator may be in a closed loop manner based on sensed information (see, for example, paragraph 0025).

With respect to claim 32, Whitehurst et al. discloses that the SCU 160 is configured to provide pulse regimes via first and second leads rather than requiring two separate stimulator housings for each lead (see Fig. 5 and associated text). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention utilize two separate stimulator housings for each lead (i.e., a first stimulator and a second stimulator), since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicman*, 168 USPQ 177, 179.

**Conclusion**

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 6,941,171 ("Mann et al.") teaches a method and system for treatment of incontinence, urgency, frequency, or pelvic pain via electrical and/or drug infusion pulses delivered to the pudendal nerves.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*NRK*  
NRK

4/3/06

*George Manuel*  
George Manuel  
Primary Examiner